IRIS Medical®
Operating Microscope Adapter
Operator Manual

IRIDEX®

13106B-EN

IRIDEX CORPORATION

1212 Terra Bella Avenue
Mountain View, California
94043-1824, U.S.A.
(800) 388-4747 (U.S. only)
(650) 940-4700

FAX:
(650) 962-0486

Customer Service:
(650) 962-8100

www.iridex.com

Contents

Introduction

About the Operating Microscope Adapter

The Operating Microscope Adapter (OMA), when connected to the OcuLight® SL or OcuLight SLx console, adds the therapeutic capability of transpupillary photocoagulation to your operating microscope.

The OMA features an integrated micromanipulator for precise targeting. It is ruggedly constructed making it ideal for the operating room environment. Additionally, its design allows for full use of your operating microscope functions.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

WARNING

Surgical lasers generate a highly concentrated beam of light, which may cause injury if improperly used. Be sure to operate the OcuLight SL/SLx console and the OMA in accordance with the procedures described in your console manual and this manual. Failure to do so may harm yourself, your patient, or others.

OMA Specifications

NOTE

Your OcuLight SL console may not be configured for large-spot delivery device compatibility.

Console compatibility

OcuLight SLx

OcuLight SL

Operating microscope compatibility

Wild/Leica (M650, M651, M690, M691, M841)

Zeiss (OPMi 1,6,19, MDO, MDU, CS with Retrolux-3, Variospot, VISU 150, and VISU 200)

Möller-Weder (Optamic 900, 900S)

Operating microscopes must be equipped with a 175 mm focal-length objective.

Treatment wavelength

Laser Diode, 810 nm

Laser spot sizes

0.3, 0.5, 0.8, 1.2, and 2.0 mm spot

Warranty and Service

Warranty

The OMA carries a standard factory warranty.

Product registration

Please complete and forward to us the enclosed product registration card.

Service and technical support

IRIDEX has established an efficient process to support its installations worldwide. Should you require assistance, please contact your local IRIDEX Technical Support representative or our corporate headquarters.

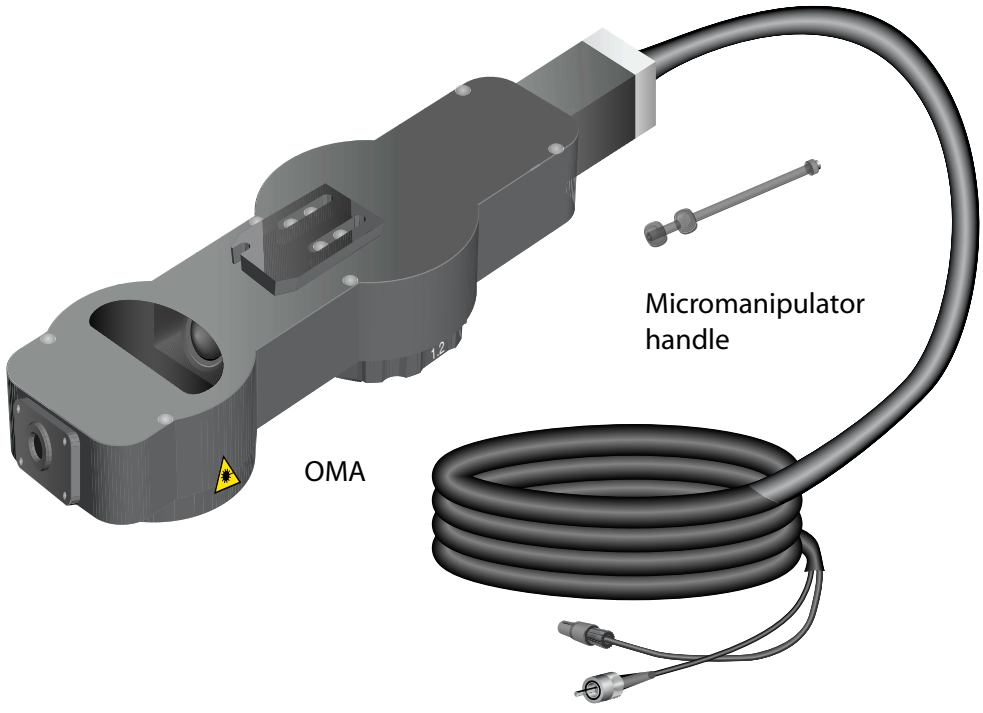
About the Components

After unpacking the contents of the OMA package, ensure that you have all of the components ordered. Check the components carefully before use to ensure that no damage occurred during transit.

Along with this manual, you should have the OMA and a micromanipulator. You may also have mounting brackets, hardware, tools, and an IRIS Medical fixed eye safety filter for the 810 nm wavelength.

Component configurations

OMA for Zeiss OPMi-1, OPMi-19, VISU 150, and VISU 200 microscopes



Fixed eye safety filter for the 810 nm wavelength

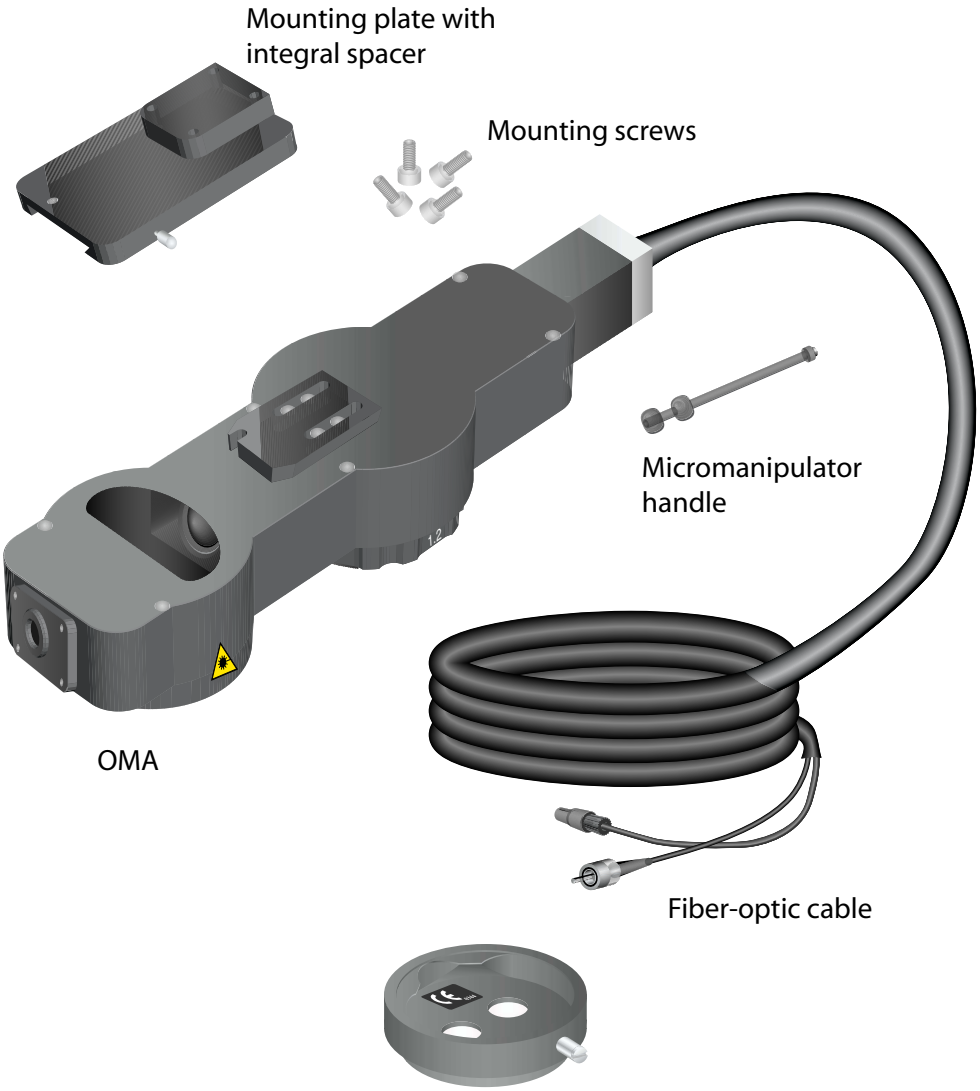
NOTE

Should you notice problems with your order, please contact your local IRIDEX Technical Support representative immediately.

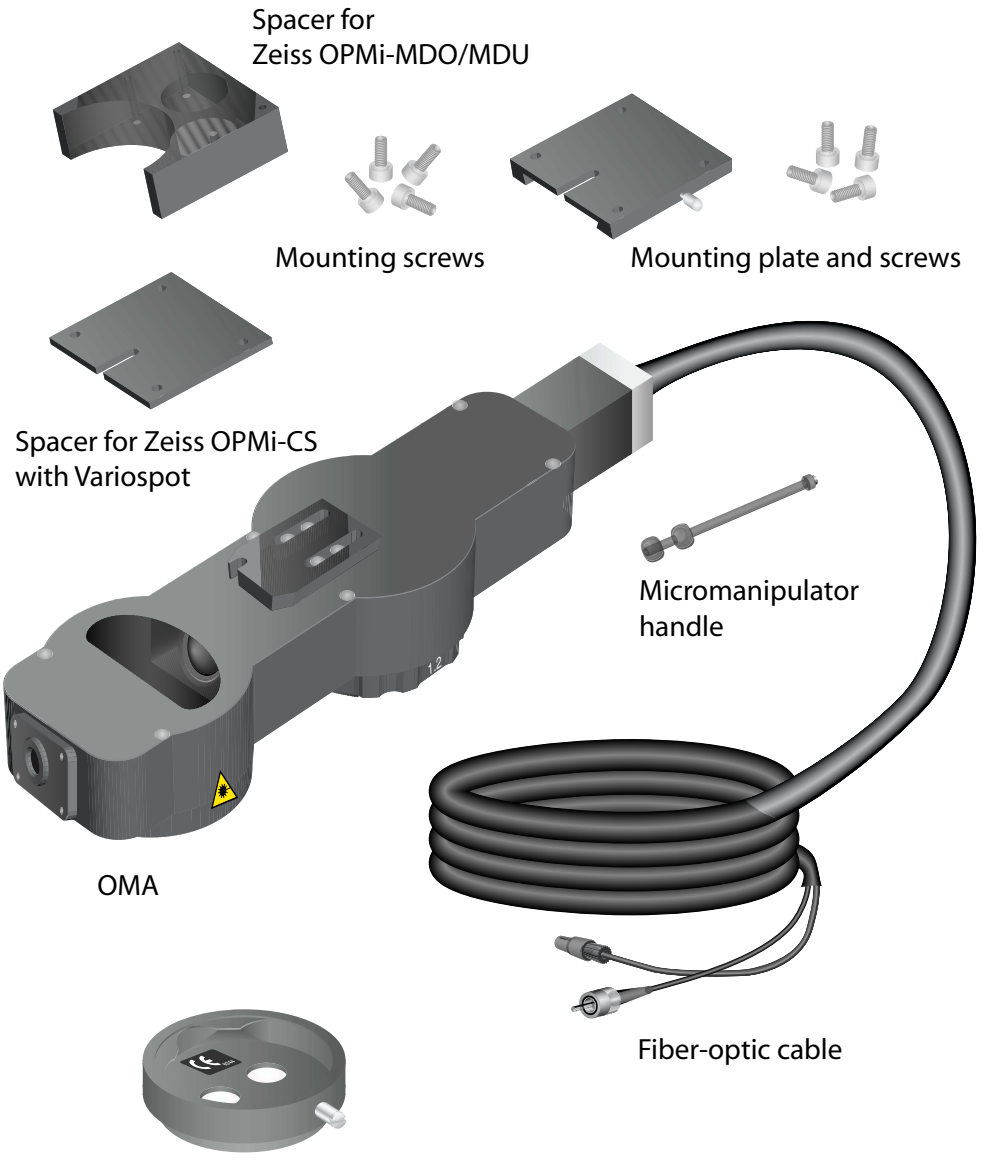
NOTE

The micromanipulator handle is secured to the OMA VISU models to prevent damage during transit.

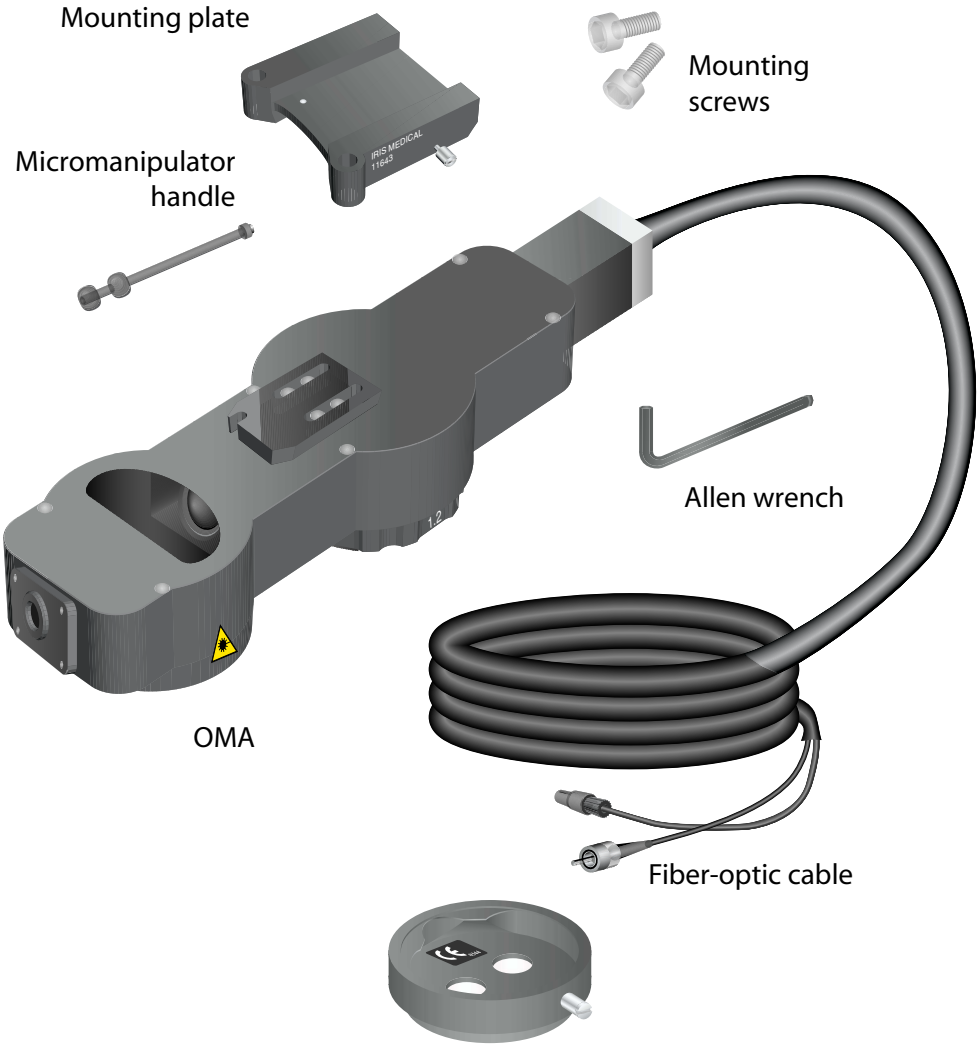
OMA for Zeiss OPMi-CS with the Retrolux-3 microscope



OMA for Zeiss OPMi-6, OPMi-MDO/MDU, and OPMi-CS with Variospot microscopes



OMA for Wild M650/M690/M841 microscopes



Fixed eye safety filter for the 810 nm wavelength

Component descriptions

OMA

The OMA attaches to your operating microscope to use it as a therapeutic device. The OMA contains the controls for adjusting the laser spot size.

Fiber-optic cable

The fiber-optic cable is part of the fiber-optic assembly attached to the OMA. The fiber-optic cable transmits the laser light through the operating microscope optics.

SmartKey®

The SmartKey is also part of the fiber-optic assembly attached to the OMA. The SmartKey communicates spot size information to the OcuLight SL/SLx console.

Micromanipulator

The micromanipulator self-centering feature adds precision beam steering capabilities to the OMA while offering a full range of motion over the treatment area.

Fixed eye safety filter for the 810 nm wavelength

The 810 nm fixed eye safety filter is silent and non-moving and has specially coated lenses that allow for a clear, unobscured, true-to-color view of the retina.

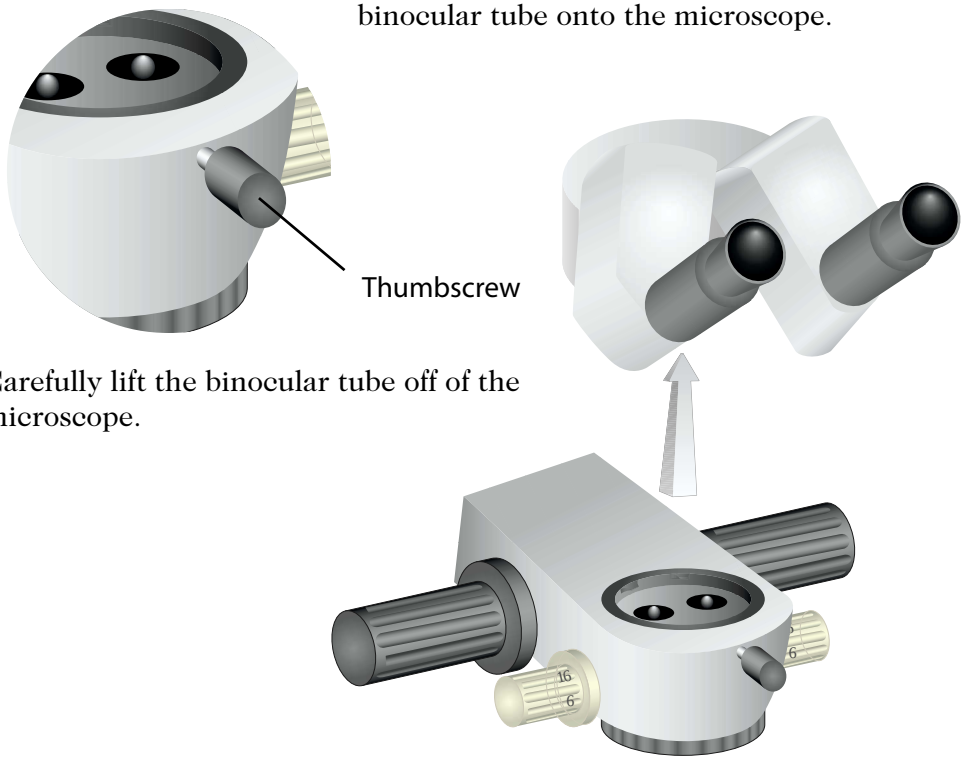
Mounting accessories

Included with some models of the OMA are mounting accessories for installing the OMA such as a mounting plate, mounting screws, and an Allen wrench.

Connecting the Components

Install the fixed eye safety filter for the 810 nm wavelength

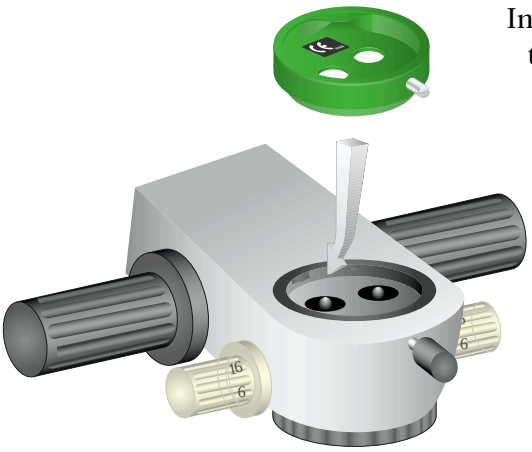
Loosen the thumbscrew that holds the binocular tube onto the microscope.



Carefully lift the binocular tube off of the microscope.

WARNING

If you are using a beam splitter, you must install the fixed eye safety filter for the 810 nm wavelength before installing the beam splitter.



Install the fixed eye safety filter for the 810 nm wavelength onto the microscope and tighten the thumbscrew to secure.

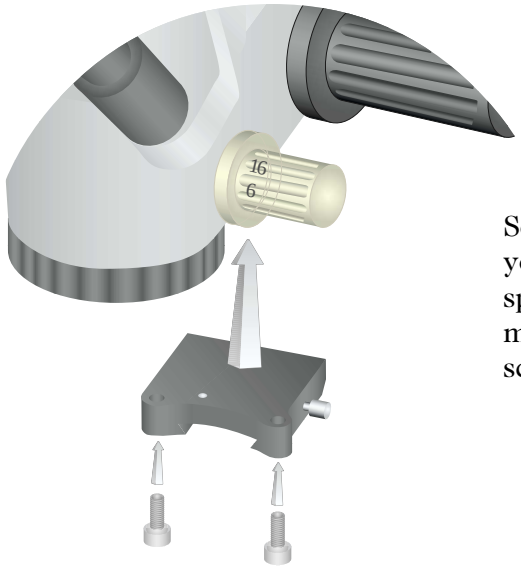
Remount the binocular tube or beam splitter into the top of the fixed eye safety filter for the 810 nm wavelength and tighten the screw to secure.

Install the OMA

Remove microscope accessories

Remove any accessories that are mounted to the underside of the microscope.

If applicable, install the mounting plate and spacer



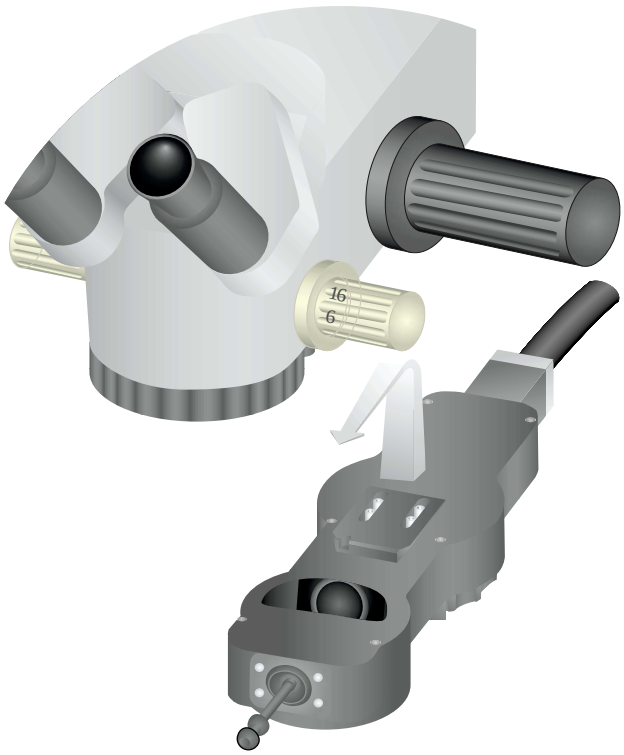
Secure the mounting plate and, if your microscope requires, the spacer to the underside of the microscope with the mounting screws.

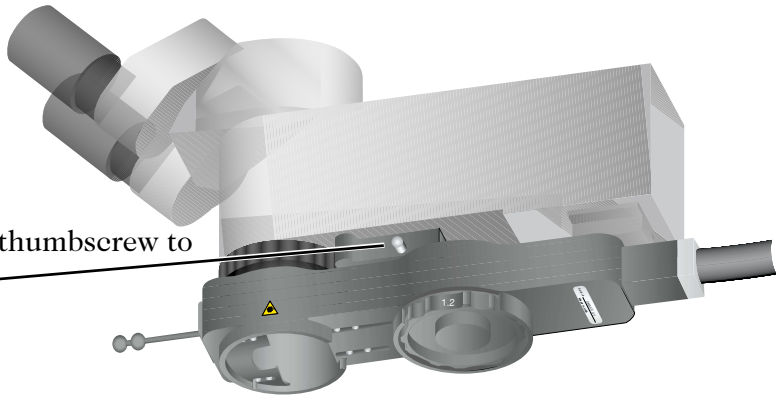
NOTE

The OMA will only work correctly if the microscope is equipped with 175 mm focal-length objective lenses.

Mount the OMA

Loosen the thumbscrew and slide the OMA into the mount until it cannot move any further.





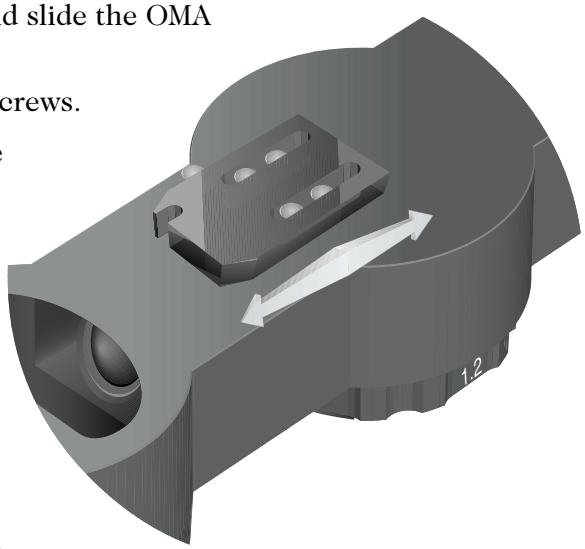
Tighten the thumbscrew to secure.

If needed, adjust the OMA

If the central field of view through the microscope is obstructed, adjust the OMA:

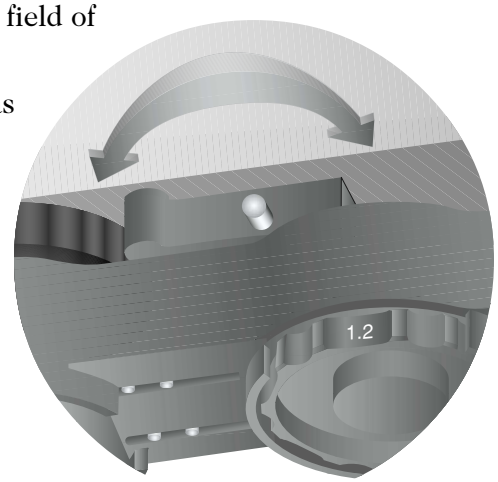
Forward and backward adjustments

1. Loosen the thumbscrew and slide the OMA out of the mounting plate.
2. Loosen the OMA dovetail screws.
3. Remount the OMA into the mounting plate.
4. Slightly move the OMA forward or backward until the field of view is no longer obstructed.
5. Carefully remove the OMA from the mounting plate so as not to affect the positioning of the dovetail.
6. Tighten the dovetail screws.
7. Slide the OMA into the mount until it cannot move any further.
8. Tighten the thumbscrew to secure.



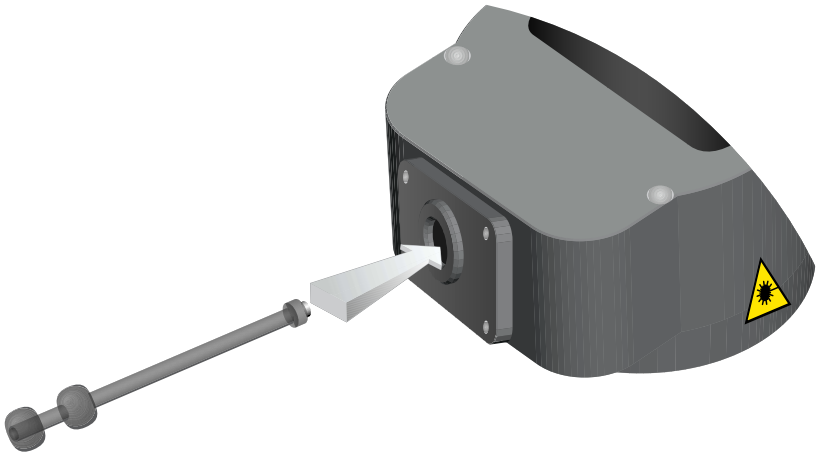
Side to side adjustments

1. Loosen the thumbscrew and slide the OMA out of the mounting plate.
2. Loosen the mounting plate screws.
3. Remount the OMA into the mounting plate.
4. Slowly pivot the OMA until the field of view is no longer obstructed.
5. Carefully remove the OMA so as not to affect the positioning of the mounting plate.
6. Tighten the mounting screws.
7. Slide the OMA into the mount until it cannot move any further.
8. Tighten the thumbscrew to secure.

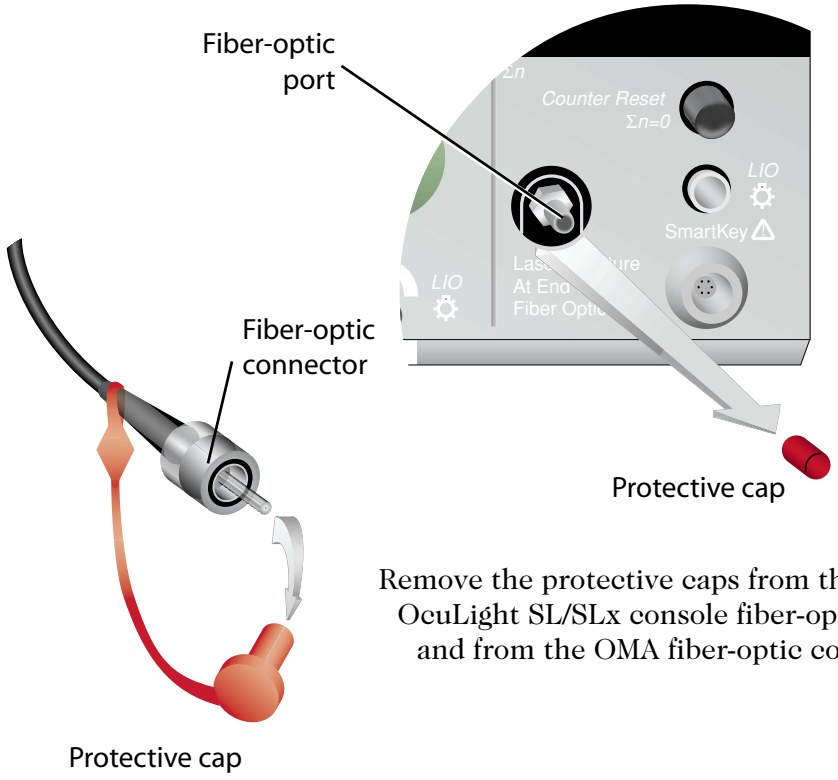


Attach the micromanipulator handle

Carefully screw the micromanipulator handle into the socket.



Connecting the fiber-optic and the SmartKey to the OcuLight SL/SLx console



Remove the protective caps from the OcuLight SL/SLx console fiber-optic port and from the OMA fiber-optic connector.

Carefully insert and finger-tighten the connector into the OcuLight SL/SLx console fiber-optic port until secure. Insert the SmartKey into the OcuLight SL/SLx console SmartKey port.

If the OMA is properly connected, when you turn on the OcuLight SL/SLx console, OMA and xxx µm (spot size) displays on the OcuLight SL/SLx console status panel.

WARNING

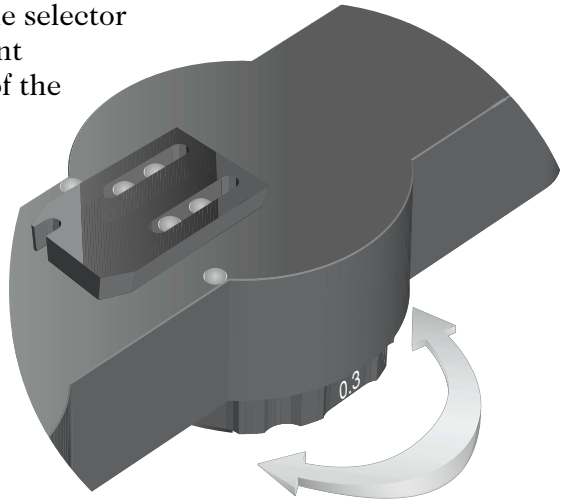
Always inspect the fiber-optic cable before connecting it to the OcuLight SL/SLx console to ensure that it has not been damaged. A damaged fiber-optic cable could cause accidental laser exposure or injury to yourself, your patient, or others in the treatment room.

WARNING

Do not use the OMA with any laser system other than an IRIS Medical OcuLight SL/SLx console. Such use may void any product warranties and jeopardize the safety of the patient, yourself, and others in the treatment room.

Selecting the Spot Size

Select spot sizes by rotating the selector to the desired position. A detent indicates the proper position of the selector.



Verifying the Focus

The OMA is preset for use with 175 mm focal-length objective lenses. Verify that the OMA is focussed:

1. Ensure that the microscope is properly set for the user.
2. Ensure that the OMA is properly positioned on the microscope and connected to the OcuLight SL/SLx console.
3. Focus the microscope on a smooth, flat object which has a matte finish.
4. Set OMA spot size to 0.3 and turn on the aiming beam.
5. Verify that the aiming beam has sharp, well-defined edges when the object is in focus.

Before Treating Patients

REFERENCE

Read the Clinical & Safety sections of your OcuLight SL/SLx console manual and this manual before using the OMA.

REFERENCE

See the Clinical and Safety sections of your OcuLight SL/SLx console manual and this manual for important IRIS Medical fixed eye safety filter for the 810 nm wavelength and safety eyewear information.

REFERENCE

See the Connecting Components sections of your OcuLight SL/SLx console manual and this manual for connection instructions.

1. Ensure that the fixed eye safety filter for the 810 nm wavelength is properly installed.
2. Ensure that the OcuLight SL/SLx console and OMA are properly connected and set up.
3. Ensure that the microscope is adjusted, as instructed by your microscope manufacturer.
4. Post the laser warning sign outside the treatment room door.

Treating a Patient

1. Turn on the OcuLight SL/SLx console.
2. Select the spot size.
3. Select and activate the operating mode.
4. Set the treatment parameters.
5. Position the patient.
6. If required, select an appropriate contact lens for the treatment.
7. Ensure that all ancillary personnel in the treatment room are wearing the appropriate laser safety eyewear.
8. Select Treat mode.
9. Position the aiming beam on the treatment site.
10. If desired, adjust the intensity of the red aiming beam.
11. Press the footswitch to deliver the treatment beam.
12. When you do not require the treatment beam, remove your foot from the footswitch and place the OcuLight SL/SLx console in Standby mode.

REFERENCE

See the Selecting the Spot Size section of this manual for instructions.

REFERENCE

See the Using the Control Panel section of your OcuLight SL/SLx console manual for instructions on using the treatment controls and displays.

WARNING

Always keep the OcuLight SL/SLx console in Standby mode when you are not treating a patient. Maintaining the OcuLight SL/SLx console in Standby mode prevents accidental laser exposure if the footswitch is inadvertently pressed.

Concluding Patient Treatment

REFERENCE

See the Inspecting and Cleaning sections of your OcuLight SL/SLx console manual and this manual for cleaning and storing instructions.

1. Place the OcuLight SL/SLx console in Standby mode.
2. If desired, record the number of exposures and any other treatment parameters.
3. Turn off the OcuLight SL/SLx console and remove the key to prevent unauthorized use.
4. Disconnect the input connector from the OcuLight SL/SLx console fiber-optic receptacle and the SmartKey. Cover the fiber-optic receptacle with the protective cap.
5. If desired, remove the OMA from the microscope.
6. If desired, clean the fiber face of the OMA's fiber-optic input connector and cover it with the protective cap.
7. If desired, clean and store the OMA. Remove the micromanipulator handle if storing in its carrying case.
8. If desired, remove the fixed eye safety filter for the 810 nm wavelength from the microscope.
9. Handle the contact lens according to manufacturer's instructions.
10. If desired, remove the laser warning sign from the operating room door.

Troubleshooting

Reporting problems

Should you experience problems with your OMA, refer to the suggestions in this section. If you continue to experience problems, write down the error message, product name, and serial number of the OcuLight SL/SLx console and the OMA before contacting your local IRIDEX Technical Support representative.

REFERENCE

See the Operation sections of your console manual and this manual for more information.

Problem	Action
Inadequate or no aiming beam	• Ensure that the OMA is properly connected to the OcuLight SL/SLx console. • Ensure that the console is in Treat mode. • Turn the Aiming Beam control fully clockwise. • Ensure that the fiber-optic connector is not damaged. • If possible, connect another IRIS Medical delivery device and place the OcuLight SL/SLx console in Treat mode. If the aiming beam is still not visible, contact your local IRIDEX Technical Support representative.
No treatment beam	• Ensure that the remote interlock has not been activated. • Ensure that the aiming beam is present and bright. • If you still have no treatment beam, contact your local IRIDEX Technical Support representative.
Does not fit on the mounting plate	• Inspect and clean the mounting plate. • Ensure the mounting plate corresponds to your microscope.

Problem	Action
Laser and viewing systems are not focussed at the same point	• Verify installation of 175 mm microscope objective lens on the microscope. The OMA has a 175 mm working distance which must be matched to the objective lens. • Turn on the aiming beam to determine whether the focus position needs to be moved closer to the microscope objective lens (raised) or moved away from the lens (lowered). Loosen the four screws so the lens can slide within the housing. Press lightly on the screws with a wrench to slightly move the lens in the direction required. Tighten the screws and check the focus position. Repeat until you achieve the desired focus.
View is blocked or partially blocked by OMA	• Set magnification to 10X or more.
The Status panel reads:	
Connect Fiber	• Ensure that the delivery device is properly connected.
No SmartKey	• Ensure that the SmartKey is properly inserted.
Spot Size?	• Ensure that the spot size selector is not between positions.

Maintenance

Inspecting and Cleaning

Routine care

- Do not tightly kink or bend the fiber-optic.
- When connected to the OcuLight SL/SLx console, ensure that the fiber-optic is located away from high traffic areas.
- Keep the micromanipulator mirror and eye safety filter windows free of fingerprints.

Inspect the OMA

Frequently inspect the OMA for dirt, debris, and damage.

Clean the fiber-optic connector

If needed, clean the fiber-optic connector using a cotton swab moistened with 100% methanol (preferred) or 100% isopropyl alcohol. Place the protective cap on the fiber-optic connector.

Clean the external surfaces

Wipe external surface of the OMA with a soft cloth dampened with a mild detergent.

Clean the micromanipulator mirror and eye safety filter

To clean the micromanipulator mirror and eye safety filter:

1. Wrap a lens tissue around one end of a cotton-tipped swab.
2. Place several drops of 100% ethanol, 100% methanol, or high-grade acetone on the tissue.
3. Wipe the lens gently with the swab to remove all dust and debris.
4. If the surface is still not clean, put a clean lens tissue around the end of the swab and gently wipe it again.

CAUTION

Turn off the OcuLight SL/SLx console before inspecting any delivery device components.

CAUTION

Always handle the fiber-optic cable with extreme care. **Do not wrap the cable in a diameter less than 15 cm (6 in)**. Damage to the fiber can impair light transmission through the fiber-optic and reduce power.

CAUTION

Keep the protective cap over the fiber-optic connector when the OMA is not in use.

Clinical Applications

Indications for clinical use

The OMA is indicated for retinal photocoagulation.

Contraindication

Do not treat albino patients.

Recommended procedure for clinical use

This section contains general guidelines and is not intended to suggest treatment techniques. Qualified physicians should review the available literature presented in clinical papers before using the OMA delivery device. A reference catalog of clinical papers and presentations is available through IRIDEX Marketing.

Power density and spot size

Tissue response to laser light is primarily determined by power density. Power density (Watts/cm^2) is laser power (Watts) divided by the area (cm^2) of the illuminated spot; therefore, you can increase power density either by increasing the laser power or by decreasing the spot size.

Power and duration

If you are uncertain of tissue response, always start at the lower power settings and increase the power and duration until you observe satisfactory clinical lesions.

Red aiming and treatment beams

Since the red aiming beam and the treatment beam come to focus at the same optical point, ensure that the aiming beam is always in sharp focus during laser delivery. An out-of-focus spot may not produce a clinically satisfactory lesion.

WARNING

The relationship between spot size and resultant power density is not linear. Halving the spot size quadruples the power density. The physician must understand the relationship between spot size, laser power, power density, and laser/tissue interaction before using the OMA.

WARNING

Excessive power settings can result in retinal holes and hemorrhages.

Excessive power with short pulse durations may result in choroidal hemorrhage.

WARNING

Tissue absorption is directly dependent upon presence of pigmentation; therefore, an eye with higher pigmentation will require lower energies to obtain equivalent results as compared to light pigmented eyes.

REFERENCE

See the Verifying the Focus section of this manual for proper focussing and set up procedures.

Safety

CAUTION

Use of controls or adjustments or performing of procedures other than those specified herein may result in hazardous radiation exposure.

WARNING

Never look directly into the aiming or treatment laser beam apertures or fiber-optic cables which deliver the laser beams with or without laser safety eyewear.

WARNING

Always verify that the OMA is properly connected to the OcuLight SL/SLx console. An improper connection may result in an inadvertent secondary laser beam. Severe eye or tissue damage could occur.

WARNING

Never look directly into the laser light source or at laser light scattered from bright reflective surfaces. Avoid directing the treatment beam at highly reflective surfaces, such as metal instruments.

Preventing unintended exposure of laser energy

To prevent exposure to laser energy, except as a therapeutic application, from either direct or diffusely reflected laser beams, always review and observe the safety precautions outlined in this manual and the OcuLight SL/SLx console operator manual before using the OMA.

Preventing unauthorized use of the system

This device is intended for use only by you, the qualified physician. The applicability of the equipment and treatment techniques selected is your sole responsibility. When you leave the OcuLight SL/SLx console and OMA unattended, turn off the system and remove the key to prevent unauthorized use.

Ensuring safe operation

Do not use the OMA if you suspect it is not functioning properly.

Connect the OMA only to an OcuLight SL/SLx console, not to any other laser. If you operate the OMA with any other laser, you could jeopardize your patient's safety, as well as your own, and void any product warranty.

Preventing reflection hazards

Laser beams reflected from specular surfaces can harm your eyes, the patient's eyes, or others' eyes. Any mirror or metal object which reflects the laser beam can constitute a reflection hazard. Make sure to remove all reflection hazards near the laser. Use nonreflecting instruments whenever possible. Be careful not to direct the laser beam at unintended objects.

Preventing fire and explosion hazards

Do not operate the OcuLight SL/SLx console and OMA in the presence of flammables or explosives such as volatile anesthetics, alcohol, and surgical preparation solutions.

Ensuring ocular protection

Protection for the physician

To protect your eyes from laser radiation when using an operating microscope with the OMA, install the IRIS Medical fixed eye safety filter for the 810 nm wavelength.

Protection for all persons in the treatment room — laser safety eyewear requirements

When using the OcuLight SL/SLx console with the OMA, a Laser Safety Officer should determine the need for safety eyewear for others in the treatment room based on the MPE, Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for the OMA and the OcuLight SL/SLx console used and the configuration of the treatment room.

Regulatory compliance safety features

The OMA complies with 21 CFR subchapter J as administered by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA).

CE-labeled devices comply with appropriate performance standards as specified in Annex II of the Medical Device Directive MDD 93/42/EEC.

Eye safety filter

The OMA requires that an IRIS Medical fixed eye safety filter for the 810 nm wavelength be placed in the viewing path of the operating microscope. The eye safety filter ensures that all laser radiation returned to the physician is below Class I limits.

Safety interlock

The OMA's protective housing and the laser fiber connector attached to the OMA cannot be opened without the use of special tools. The OMA is also safety interlocked at the fiber coupler on the OcuLight SL/SLx console.

WARNING

Do not operate the OcuLight SL/SLx console and OMA in the presence of flammables or explosives such as volatile anesthetics, alcohol, and surgical preparation solutions.

WARNING

Ensure that all persons in the treatment room are wearing the appropriate laser safety eyewear. Never substitute prescription eyewear for appropriate laser safety eyewear.

REFERENCE

See your OcuLight SL/SLx console manual for more information about the formula used to calculate the worst case NOHD for the OMA and the OcuLight SL/SLx console in use.

REFERENCE

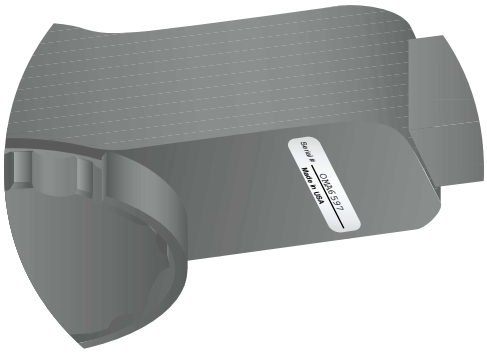
For further information, you may refer to: IEC 60825-1: and ANSI Z136.1.

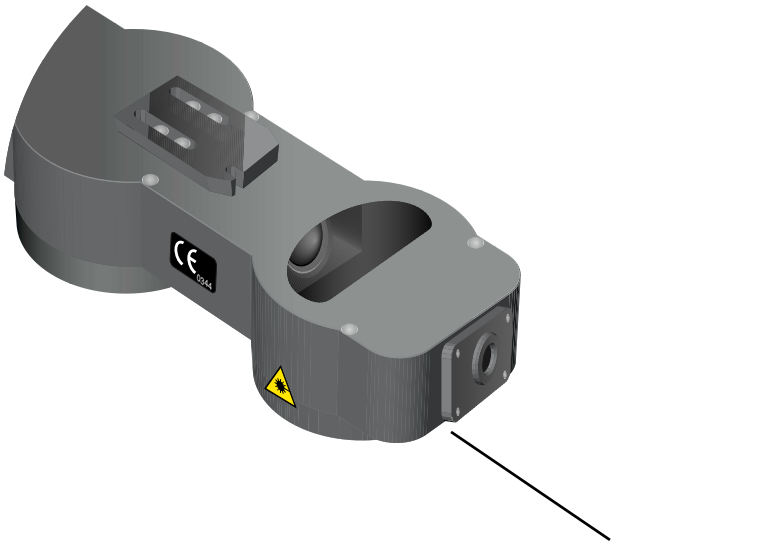
Location of regulatory compliance and other system labels

Serial Number label

Serial # OMAxxxx

Made in USA





Laser Aperture labels

CE label

CE 0344